A I D S
TREATMENT
N E W S

Issue Number 394
September 12, 2003

Published 18 times a year by
John S. James
AIDS Treatment News
1233 Locust St., 5th floor

# Contents

# AIDS Treatment News

**Subscription and Editorial Office:**
AIDS Treatment News
Philadelphia FIGHT
1233 Locust St., 5th floor
Philadelphia, PA 19107
800-TREAT-1-2 toll-free U.S. and Canada
fax: 215-985-4952
email: aidsnews@aidsnews.org

**Editor and Publisher**: John S. James
**Reader Services:** Allison Dinsmore

**Statement of Purpose:**
*AIDS Treatment News* reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations that work for them. *AIDS Treatment News* does not recommend particular therapies, but seeks to increase the options available.

**Subscription Information: Call 800-TREAT-1-2**

Businesses, Institutions, Professional offices: $325/year. Includes early delivery of an extra copy by email.

Nonprofit community organizations: $150/year. Includes early delivery of an extra copy by email.

Individuals: $140/year, or $80 for six months.

Special discount for persons with financial difficulties: $54/year, or $30 for six months. If you cannot afford a subscription, please write or call.

Outside the U.S., Canada, or Mexico, add airmail postage of $20/year, or $10 for six months.

Back issues, and discounts for multiple subscriptions, are available; contact our office for details.

Please send U.S. funds: personal check or bank draft, international postal money order, or travelers checks. VISA, Mastercard, and purchase orders also accepted.


controlling their virus because it had extensive resistance to HIV drugs.

### New Guidelines for Avoiding Heart Disease by Managing High Cholesterol, Triglycerides, or Related Problems in HIV.....

These guidelines, based on new heart guidelines for the general public and including HIV-specific issues, have many useful suggestions.

## WTO Accepts Rules Limiting Medicine Exports to Poor Countries

by John S. James

On August 30, 2003, a World Trade Organization (WTO) meeting in Geneva, Switzerland adopted new rules on exporting generic copies of patented drugs to poor countries. The WTO and some of its trade delegates presented these rules as a grand humanitarian solution that will now make AIDS and other medicines more available to the poor. In fact, almost everything in the texts was written on behalf of multinational pharmaceutical corporations, and demanded for their benefit by the United States and to a lesser extent by European and other rich countries. The pharmaceutical industry, with the U.S. government in tow, won the decision by splitting the richer from the poorer developing countries and bringing great pressure to bear, while most of the international-trade establishment just wanted this issue off the table one way or another.

Organizations actually providing treatment in developing countries fear that the new system will obstruct access, and that poor countries that cannot manufacture their own pharmaceuticals will be worse off in the future. Médecins sans Frontières (Doctors Without Borders, the worldwide relief organization that won a 1999 Nobel prize for its work) and Oxfam

(a major British famine-relief organization) said in a joint press issued August 30, 2003, "Today's WTO agreement that is ostensibly intended to get drugs to the poorest countries does not provide a workable solution. [It] was designed to offer comfort to the U.S. and the Western pharmaceutical industry.... Unfortunately, it offers little comfort for poor patients. Global patent rules will continue to drive up the price of medicines....Yesterday, over twenty developing countries were voicing concerns about the text. Today, they have come under tremendous pressure to adopt it. However, this disappointing outcome must not prevent countries from immediately taking measures that are allowed under WTO patent rules in order to access affordable medicines and save lives."

The one victory of the developing countries was the elimination of a disease list -- which would have banned all pharmaceutical exports of generic copies of patented drugs for any disease except AIDS, tuberculosis, malaria, and a short list of others, mostly tropical infections that are not commercially important in rich countries. If the U.S. had had its way, exporting generics of patented drugs for cancer, diabetes, asthma, and almost all other diseases, even to the world's poorest countries, would have been flatly prohibited. In December 2002 the U.S. alone blocked world agreement at another World Trade Organization meeting by demanding the disease list. But developing countries would not accept it, so the proprietary pharmaceutical industry decided to change its strategy and rely on other restrictions instead.

The most important fact about all pharmaceutical trade rules is that in case of a catastrophic emergency in the U.S. or other powerful countries, such as a major chemical or biological attack or deadly epidemic, these countries will do whatever they need to do, and none of the rules will be worth the paper they are written on. But this basic assurance is not available to developing countries, for whom over 20 million dead of AIDS does not rise to that level of emergency. If rich and powerful governments did not have a pass when it counts, but were truly bound by the rules they make others obey even at the sacrifice of lives, then the entire design and content of the rules would be different -- a central reality known to all but usually absent from analysis and discussion.

See our References below for links to the full text of the August 30 agreement [1, 2], the WTO August 30 press release [3], and to the Doha Declaration [4], a WTO agreement two years ago that trade rules should not prevent countries from protecting public health.

## Historical Context

Most new medicines are patented for up to 20 years, and patent holders can charge any price they want -- commonly $10,000 or more per patient per year for HIV treatment in the United States (up to 20 times what a generic manufacturer could charge and still make a profit). Because they are new, all antiretrovirals are patented in rich countries, and in most other countries where a viable market could exist. Usually patent holders have no incentive to market their drugs in poor countries -- but do not want generic manufacturers or anyone else doing so, because the example of low-cost drugs might upset their markets in rich countries, especially the U.S. Millions died without treatment in poor countries while the issue of treating them with patent-protected drugs (the only ones available) was mostly kept off the table until about four years ago.

Patent laws are national, not international, but the trade agreement that formed the WTO demands that all countries conform their patent laws to the European system, and include patents on pharmaceuticals, which had not been required before 1995. Developing countries were given until 2006 to change their patent laws to comply fully with the new rules (recently extended to 2016 for least-developed countries); this is why

India, for example, can manufacture and export AIDS drugs today. (India allows patenting of a drug manufacturing process but not of the final molecule -- a successful system to encourage domestic industry to compete in low-cost drug production. But India will have to change its patent laws by 2006, and then generic exports of new medicines will no longer be allowed except under the new rules just adopted.)

Existing WTO rules allow a country to use "compulsory licensing" (granting the right to manufacture a patented product without the patent-holders consent) under certain conditions -- and to *import* a drug under a compulsory license. But these rules also say the drug must be manufactured primarily for domestic use -- so starting in 2006 or some time before then, there might be no one legally able to *export* the drug even to a country allowed to import it. Since poor countries usually cannot pay the patent-holder's price, and cannot make the drugs domestically, how could their people obtain new pharmaceutical treatments? This "export problem" has been a major trade controversy for over two years, and was the reason for the WTO meeting of 146 countries that just adopted the new rules.

In November 2001 all countries in the WTO accepted the landmark "Doha Declaration," which said, "We agree that the TRIPS agreement [the WTO's intellectual property rules] does not and should not prevent members from taking measures to protect public health." The August 30 rules were supposed to implement the Doha Declaration, but instead they restricted it. For example, the 10 nations that hope to join the European Union (mostly poor countries in Eastern Europe) "agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency" [2] until they join the EU -- and then that they will not import generic versions of patented pharmaceuticals even in such an emergency. (The countries are Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic, and Slovenia.) Pressuring these countries not to respond even to a national emergency in order to protect profits of pharmaceutical companies is hardly an "implementation" of the Doha Declaration that trade rules should not prevent countries from protecting public health.

## Reactions For and Against the New WTO Export Rules

Here are some quotes that show the great differences of opinion about the new trade rules on pharmaceuticals. Basically, everyone says that they want to help poor countries get treatment -- but that is where the semblance of agreement ends.

The following background will help those not familiar with this complex issue to understand the quotes below:

* The WTO ratifies decisions by unanimous consensus of all 146-member countries. But the actual decisions are made in small, secret meetings set up by the U.S. and other powerful countries, to craft agreements that they want, and may be able to get through the whole body. Then great pressures are used to bring everyone into line -- especially by the world's only superpower, whose decisions affect every country in countless ways.

* In this case five countries negotiated the text that the others had to accept or reject without change; these countries were the U.S., Brazil, India, Kenya, and South Africa. Clearly the U.S. had the most instruments of pressure at its disposal. The other four countries will be able to produce many pharmaceuticals domestically, so the lives of their citizens were not at stake in the decision, as they are for many poor countries. India will lose some business if the rules prove mostly unworkable -- but its potential revenue from sales to the poorest countries is not great, and far less than its potential sales to the U.S. [5] (provided India stays on good terms with the superpower). And once these four countries accepted the U.S. demands, they were removed as potential leaders of any movement by developing countries to get an agreement more in their interest.

* Once a government has accepted a WTO

agreement (for any reason), it is not going to criticize it in public, no matter what it thinks internally. Therefore official statements from rich and poor countries alike can be expected to be supportive. Those who work in health care in developing countries may or may not be free to speak publicly about what they know.

* The U.S. and some international press, unfamiliar with the background of this issue, mainly reported the WTO position, presenting the new rules as a great humanitarian advance. But activists working in the area see the whole point of this agreement as stopping the development of low-cost trade among poor countries in generic versions of medicines protected by patents in rich countries -- sacrificing lives to protect a dysfunctional business model that denies new medical advances to most of the people who need them.

* Poor countries even more than rich ones had strong incentives to get this issue out of the way before the crucial WTO meeting beginning September 10 in Cancún, Mexico. They desperately want reforms in other areas, especially agricultural trade rules. Rich countries spend over $300,000,000,000 (300 billion dollars) every year supporting their farmers[6], mostly big corporations -- undercutting lower-cost producers in developing countries that cannot pay such support, and keeping whole nations and regions in poverty.

* "TRIPS" is the "Trade-Related Aspects of Intellectual Property Rights," the part of the WTO agreement that deals with patent, copyright, and related laws; it took effect on January 1, 1995. Though TRIPS was designed with no thought whatever to its effect on access to AIDS or other treatment in poor countries, it does contain general safeguards that activists have used to argue for access, or against worse restrictions (sometimes called "TRIPS-plus") that the U.S. is imposing through other treaties. For technical background on TRIPS, see:
http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

* Almost all patents are held in rich countries (for reference and discussion see *BMJ* (*British Medical Journal*) September 13, 2003,
http://bmj.com/cgi/content/full/327/7415/571?etoc
Therefore pharmaceutical patents bring no commercial benefit to most poor countries but only raise the prices of drugs -- or more likely exclude all but the elite from new medicines entirely. Patents can help motivate research and development of new drugs -- but only for those who can buy them at high prices.

* The August 30 agreement is temporary, to be replaced by mid 2004 with a permanent amendment to TRIPS that "will be based, where appropriate, on this Decision" [2]. So the issue must be revisited next year. There may be no real test of the rules by then, however -- since legally these rules act by providing a waiver of an existing WTO rule, and the countries that have been exporting AIDS drugs will not need the waiver by that time. On the other hand, a generic manufacturer in a rich country that is already required to comply fully with TRIPS (such as Canada, where at least one company has been interested in producing AIDS medicines for poor countries but has been blocked by Canadian law) might be able to use the new WTO rules now. (In this instance, Canada would need new legislation before any of its generic companies could try to use compulsory licenses -- and the much richer proprietary pharmaceutical industry that largely wrote these rules would probably oppose such amended legislation.)

* An urgent task now and for the next year is to find possibilities that might work under the new rules (or work around them) to deliver treatment to poor countries, and make sure that critical doors are not closed when the permanent TRIPS wording is devised. The final wording might not be public until just before the vote, but still health activists can educate the international-trade community about what provisions are most important for access to medical care, and why they matter.

## Range of Views on the Issue

* "The two decisions that the General Council reached today -- the Motta text [1] [named for a WTO official] and the Chairman's statement [2] -- will ensure that the system will not be abused. The additional clarifications contained in the Chairman's statement [The General Council

Chairperson's Statement] add strong provisions to prevent diversion, and increase the likelihood that the solution will benefit patients in the world's poorest countries as envisioned in the Doha Declaration. Taken as a whole, this solution reaffirms the critical role of patents in the development of new medicines." -- Pharmaceutical Research and Manufacturers of America (PhRMA), August 30, 2003 press release. [IFPMA, the International Federation of Pharmaceutical Manufacturers Associations, also released a press statement supporting the decision.]

* Law professor and Health GAP member Brook Baker explained the procedures that will be required under the new rules: "In order to import medicines in a country where a drug has been patented, the following steps must be followed: (1) the importing country must seek a voluntary license on commercially reasonable terms for a commercially reasonable period of time; (2) failing that someone must apply for a compulsory license; (3) if the compulsory license is for import, the importing country must assess its generic industry's capacity to produce the medicine locally; (4) if capacity is insufficient, it must notify the WTO of its decision and explain and justify its decision re capacity in detail; (5) the importing country must notify a potential exporter; (6) that exporter must in turn seek a voluntary license on commercially reasonable terms for a commercially reasonable period of time; (7) that exporter must seek a compulsory license from its own government on a single-country basis; (8) compensation by royalty must be set based on standards of reasonableness in the importing country; (9) if a license is granted, the exporter must investigate pill size, shape, coloring, labeling, and packaging of the patent-holder's product in the importing country and differentiate its new product in all respects, regardless of cost; (10) obviously, the generic producer will need to seek product registration and prove bio-equivalence based on a pill of different size and shape. This process must be fulfilled over and over again for each and every drug and for each and every country to which the drug will be exported. This procedural nightmare may create a cottage industry for lawyers, but it will not expedite the delivery of affordable medicines to people dying of treatable diseases." -- "Vows of Poverty, Shrunken Markets, Burdensome Manufacturing and Other Nonsense at the WTO," August 28, 2003, http://lists.essential.org/pipermail/ip-health/2003-August/005176.html

* "All people of good will and good conscience will be very happy today with the decision that the WTO members have made. It's especially good news for the people of Africa who desperately need access to affordable medicine." -- Kenyan Ambassador Amina Chawahir Mohamed, quoted in *The Washington Post*, August 31, 2003.

* "America is arm-twisting. It's a triumph for corporate greed." -- Gitura Mwaura, chair of the Kenya Coalition for Access to Essential Medicines, quoted by Reuters, August 28, 2003 and published in *The New York Times*. Another Kenyon quoted in the same article, Gichinga Ndirangu, trade communication manager for the Heinrich Boll Foundation in Nairobi, said "they just outflanked the developing countries."

* "This will absolutely save millions of lives that would be lost without it." -- Faizel Ismail, South Africa's representative to the WTO, *The New York Times*, August 31, 2003.

* "The sense is really that it is way too much red tape, and that it is not a feasible solution to the problem." -- Jonathan Berger, AIDS law project at Witwatersrand University, Johannesburg, South Africa, quoted by Reuters, August 28, 2003.

* "We are under tremendous pressure. It's a question of whether other countries will assent to the fact that this is as far as the U.S. government is willing to go. The deal is on the table and the U.S. attitude is, 'Take it or leave it.'" -- Trade ambassador from "a large Asian country whose government had raised concerns about the plan," *The Washington Post*, August 30, 2003.

* "You cannot expect every poor country in the world to produce lifesaving drugs. There is no question that to get access, we are going to have to allow countries to import generic drugs from richer countries." -- Michael H. Merson, dean of the public health school at Yale University, quoted in *The*

*Washington Post*, August 30, 2003.

* "The solution could have been very simple and straightforward, using a model such as the World Health Organization and other experts have suggested. The complexities imposed by rich countries are designed to uphold drug company monopolies and to discourage widespread generic competition in poor countries." -- Gaelle Krikorian, Act Up-Paris, joint press release by ACT Up Paris and Health GAP, September 11, 2003.

* "No matter how desperate the health need, a developing country without the capacity to produce a needed drug (which is virtually all of them) will have to ask another government to suspend the relevant patent and license a local company to produce and export it. Few countries, if any, will be prepared to help other countries in this way, as it would provoke retaliation by the US which fiercely defends the commercial interests of the pharmaceutical corporations.

"Furthermore, the agreement is wrapped in so much red tape that it becomes largely unworkable - it amends a clause of only 20 words, yet runs to more than seven whole pages. In practice, most poor countries will end up paying the high price for patented medicines or, most probably, doing without." -- Oxfam, "WTO Patent Rules Will Still Deny Medicines to the Poor," press statement August 27, 2003.

* "The current decision is only a temporary waiver, and a permanent amendment to the TRIPS is scheduled for 2004. We call upon the WTO member countries to draft an amendment to the TRIPS that simplifies and clarifies the procedures and removes unnecessary obstacles to the export of medicines to address public health problems." Joint statement on TRIPS and public health, September 10, by 14 non-government organizations in Cancún: ACT Up Paris; Consumer Project on Technology; Consumers International; Essential Action; European AIDS Treatment Group; Health Action International; Health GAP; International People's Health Council; Médecins sans Frontières; OXFAM International; People's Health Movement; SEATINI; Third World Network; Women in Development

* "They're playing with fire. The sensitivities of this are obvious and we're right on the edge here." -- Jon Huenemann, former U.S. assistant trade representative, quoted in *The Wall Street Journal,* September 5, 2003 on Brazil's plan to use compulsory licensing to authorize government importing of three generic drugs for HIV (efavirenz, lopinavir, and nelfinavir) until it can make sufficient quantities domestically, unless the patent holders will give Brazil a larger discount. Brazil now pays 63% of its AIDS drug budget for these three alone. [For technical reasons Brazil's plans are not directly related to the new WTO rules; we included this quote to show the emotion around the issue.]

In 2001 the U.S. itself threatened to use compulsory licensing of pharmaceuticals (which it normally opposes) to import a generic version of an antibiotic for anthrax at a lower price, when the drug was under patent in the U.S. but not in other countries. AIDS has killed over a million times more people than the anthrax attacks in the U.S.

## Comment

Today epidemics are more dangerous than before, due to higher population densities and greatly increased long-distance travel. At the same time scientific and medical advances offer more opportunities than ever to control disease and enable people to live longer and healthier lives. The key stumbling block is the lack of political will to deal with illnesses that mostly affect the poor. It is appalling that instead of responding to these problems and opportunities, the WTO has adopted language clearly written by industry to prevent "South-South" (poor country) generic trade in new medicines, eliminating or greatly restricting some of the most useful options for public health before they even come into view.

The problem of diversion of the drugs for the poor into rich countries (a main argument for the new rules) is mostly a smokescreen. Diversion has been minor and easily controlled, since the pills of all legitimate manufacturers must already look different. But even if this issue were significant, governments and the WTO should prioritize public health over corporate revenue.

The biggest single obstacle to global

health today is lack of resources -- including funding, infrastructure, training, and rational procurement and distribution systems for medicines. Pharmaceutical patents -- and the worldwide dark cloud of restrictions that flow from them, blocking medical research as well as access to treatment -- may be number two or three. Both have a common root in the lack of political will.

The central problem in AIDS is political, as it has always been. No law of nature prevents the most powerful business and government leaders from applying their influence and creativity on behalf of the common good as well as private interests. A completely different perspective is possible. If people could organize the political and institutional will to save lives and make systems that work for everyone, then it would not be hard to assemble the needed resources, build medical infrastructure, deal with stigma, trade restrictions, and other problems, and get the global epidemics under control.

Note: Kate Krauss of AIDS Policy Project [http://www.aidspolicyproject.org] contributed to this article.

## References


(1) Text of "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" -- rules limiting medicine exports, adopted August 30, 2003:
http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
(Also see reference 2, below.)

(2) Additional rules favoring pharmaceutical companies were issued in "The General Council Chairperson's Statement," August 30, 2003:
http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm

(3) World Trade Organization press release, August 30, 2003:
http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

(4) Full text of the November 2001 Doha Declaration on the TRIPS Agreement and Public Health, November 20, 2001:
http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

(5) *The Economist*, September 6, 2003, "Indian Pharmaceuticals: Patently Ambitious," page 56.

(6) The $300 billion figure is from *The Economist*, September 6, 2003, "The Cancun Challenge," pages 59-61.


# Mother-to-Child Transmission Better Than AZT -- At 70 Times Less Cost

# Nevirapine Reduced

A single dose of nevirapine given to an HIV-positive woman during labor, and a single dose given to her infant soon after birth, reduced HIV transmission 41% better than AZT when the infants were age 18 months, in a study conducted by researchers at Makerere University in Kampala, Uganda, and at the U.S. National Institute of Allergy and Infectious Diseases (NIAID) [1]. About 26% of the children in the AZT group were infected by 18 months, vs. about 16% of children in the nevirapine group. The AZT regimen consisted of one or more doses to the women during labor, and twice-daily doses to the infants during their first week. The simpler nevirapine treatment cost about 70 times less than the AZT treatment.

Nevirapine did not seem to have any long-term antiviral effect. Rather, it gave better early protection when the infants were most vulnerable to infection. After the treatment, infants in both groups continued to get infected at about the same rate due to breastfeeding, which most of the women had stopped by 18 months (the average time breastfeeding was nine months).

An accompanying editorial suggested that two to three days of AZT plus 3TC could be added to the mother's treatment to prevent development of viral resistance to nevirapine, which can happen when even a single dose of nevirapine is used alone. Or, much better, the mothers could be started on combination antiretroviral treatment [2].

About 800,000 children are infected with HIV each year through mother-to-child transmission, and hundreds of thousands of these cases could be prevented. Cost of the nevirapine is not the problem. The main obstacle has been funding and implementing the programs to use it (which usually require testing, counseling, dealing with stigma such as violence against women who test positive, staff training, prenatal care, and associated infrastructure). Only about 1% of Africans now have access to services for prevention of mother-to-child transmission of HIV, according to a World Health Organization report issued September 1, 2003.